NOV 0 6 2001

K010739

Itamar Medical Ltd
510(k) Submission
Watch Pat 100 System Diagnostic Aid for Sleep Disorders

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements Regulation par. 807.92, effective March 14, 1995.

1. Submitter

Name: Itamar Medical Ltd.
Address: 2 Ha'eshel St, Caesarea 38900 Israel
Telephone Number: 972-4-617-7000
Contact person: Dr. George Myers, 210-787- 1703
Date prepared: March 1, 2001

2. Device

Proprietary name: Watch Pat 100 System
Common Name: Apnea/Hypopnea Diagnostic Aid
Classification Name: Monitor (Apnea Detection), Ventilatory Effort

The WATCH PAT ™ 100 (WP 100) is a patient-worn device for aiding the diagnosis of obstructive sleep apnea syndrome based on Peripheral Arterial Tonometry (PAT), and an associated computer analysis program.

3. Predicate Devices

Mesam IV recorder, K904166
Embla, K971813

4. Description

The WATCH PAT ™ 100 (WP 100) is a patient-worn device used at home for aiding the diagnosis of obstructive sleep apnea syndrome based on Peripheral Arterial Tonometry (PAT), a non-invasive technology. The controller part of the device is worn on the wrist, and continuously measures the relative state of the vasomotor activity in the distal part of the finger by a finger-mounted probe based, on an optical plethysmographic method. The measured signal is acquired from a self contained, opto-pneumatic sensor, designed to cover the distal part of the finger with a uniform pressure field extending to the very tip of the finger. The unit has a PC program that provides the Respiratory Disturbance Index (RDI), the number of events per hour of sleep.

5. Intended Use

The Watch PAT 100 device is a non-invasive home care device, intended for use as a diagnostic aid in the detection of sleep related breathing disorders. It is indicated in cases of suspected sleep disorders.

The Watch PAT 100 is not indicated for children less than 17 years old.

The Watch PAT 100 is contraindicated for patients with latex allergy

6. Comparison

The Watch Pat 100 uses the same technology as the Mesam IV recorder. In a clinical test, the scoring of the system was compared to the automatic scoring of the Embla system.

7. Performance Data

(1) Non-clinical tests

The Watch Pat 100 has had the tests for EN60601-1 and EN 60601-1-2, as well as EN vibration tests, and has had its software validated.

(2) Clinical Tests

In a clinical tests, the Watch Pat 100 and the Embla with automatic scoring were compared each other and with manual scoring.

8. Conclusion

The conclusion drawn from these tests is that the Watch Pat 100 is equivalent in safety and efficacy to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 6 2001

Mr. George H. Myers
Itamar Medical (C.M.) 1997 Ltd.
c/o Medsys Inc.
377 Route 17
Hasbrouck Heights, NJ 07604

Re: K010739
Watch-Pat 100
Regulation Number: 868.2375 and 870.2780
Regulation Name: Breathing Frequency Monitor and Hydraulic, Pneumatic or Photoelectric Phethysmograph
Regulatory Class: Class II (two)
Product Code: 73 MNR and 74 JOM
Dated: March 7, 2001
Received: March 12, 2001

Dear Mr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K010739

Device Name: Watch PAT 100 Device

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The Watch PAT 100 is not indicated for children less than 17 years old.

The Watch PAT 100 is contraindicated for patients with latex allergy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010739